Information Sheet for Ancillary Reviewers

This information sheet will provide you with instructions for your role as an ancillary reviewer. Email us at irb@pitt.edu if you need assistance.

Notification of Required Review

- Email notification
  - You will receive an email notification indicating the need for your ancillary review, provide a link to OSIRIS, and also include the PI’s name and study title
- Log onto OSIRIS
  - All users must have completed 2 education modules (Research Integrity and Human Subjects Research) before access to OSIRIS is permitted
  - Need assistance
    - Email us at irb@pitt.edu

Login

- Go to https://www.osiris.pitt.edu
- Click on Login (top right-hand corner of page)
- Enter Username (email address) and Password as registered with HSConnect
- If you have Forgotten your password
  - Click on link available from the login page and HSConnect will email your username and password to you
  - Go to https://www.osiris.pitt.edu and Login again
- To end your session, click the Logoff button (top right-hand corner of page)

Overview of ancillary reviewer workspace

- Under My Roles (located on the left-hand side of the page)
  - Select Ancillary Reviewer role as you may have multiple roles

- My Tasks tab located in mid-section of the page
  - Displays all projects you are required to review
  - Click on the hyperlinked title of the project you wish to review
  - You can return to page displaying My Tasks anytime by clicking on My Home tab located in the top right hand corner of the page

- Studies, Modifications, and Renewal
  - Lists all projects for which you have access to review and includes a Search function
    - Filter by allows you to search by Study ID, Study Name, PI last or first name, or State of submission and then type in the information
    - If you wish to enter only part of the number or name, insert the % sign prior to the number or letters to conduct the search
    - Click on the hyperlink for ID, Name, Date Modified, or State to change the order of display (e.g., date modified = display the oldest or newest project first)

Overview of study workspace

- Current State located on the left hand side of the page
  - Lists the review state of the project (e.g., Ancillary, IRB Review, Approved)
- Edit Study displays the page by page view of the smartform questions
- Reviewer Version displays the summary version of all smartform questions and PI responses. It does not display the Help Text normally available from the right hand side
- View Smartform Progress provides a process whereby the investigator can make sure all the required smartform questions have been addressed

- My Activities displays all the functions the ancillary reviewer is permitted to perform
  - Changes Requested by Ancillary Reviewer
• Permits the investigator to respond to your comments
  ▪ The application is locked down and editable by the investigator only if the
    reviewer request changes
  o Approve Application by Ancillary Reviewer
    ▪ Ancillary reviewer approves the application and no changes are permitted
  o Terminated
    ▪ The application is stopped and no further reviews will occur
  o Send Comments to Study Team
    ▪ Use only to send general comments to the investigator which do not require
      changes to the application

• Study Views
  o History tab
    ▪ Displays all the past activities associated with the study
  o Pre Review tab
    ▪ Displays all the required pre-IRB reviews indicating whether approved or pending
      approval
  o Attachments
    ▪ Displays specific documents/forms uploaded by the investigator (e.g., consent(s),
      sponsor protocols/brochures, grant applications, questionnaires)
  o Change Log tab
    ▪ Displays all changes to smartform questions but not the changes to uploaded
      documents

Initiate your review

There are 2 sections you will need to access in order to conduct your review: Reviewer Version
  and the Attachment section.

• Click on Reviewer Version button located on the left-hand side of the page
  o Provides a view of the entire OSIRIS application on one continuous page
    ▪ When you have completed your review, click on the browser’s back button located
      at top right-hand corner of the page which will close the browser and you will be
      returned to the summary page

• Click on the Attachments tab available from the mid-section of the summary page
  o Contains all uploaded documents (e.g., grant, sponsor’s documents, drug/device
    brochures, consent forms, fiscal review forms) which may be necessary for your review

• When writing your comments, please remember to identify the question for which you are
  commenting
  o For example, 4.1 Will potential research subjects be identified through the use of
    advertisements?
    ▪ Sample reviewer comment: 4.1 - You failed to include the advertisements for
      review and approval

Send questions or comments to the PI

• Under My Activities section of a project’s workspace
  o Click on Changes Requested
    ▪ A textbox is available to add your requests or you may cut and paste from
      another document
    ▪ Another option is to upload a memo/letter with the requested changes
    ▪ The process of requesting changes unlocks the project and allows the investigator
      to make the requested changes
    ▪ OSIRIS automatically sends an email notification to the PI and Study Coordinator
      notifying them of your request

• Instructions for uploading a document (e.g., guidance document, memo/letter, forms)
  o Click on the Add button
- **Browser window** will open
- Title: add the title of the document
- File: click on Browse and upload the document (e.g., desktop, computer file)
- Click OK to upload the document into OSIRIS

### Response to comments and approval determination

- The PI will submit the changes for your review
- You will receive an **Email notification**
  - The email notification will indicate the investigator has responded to your comments, provide a link to OSIRIS, and include the investigator's name and study title
- **Logon** to OSIRIS
- Click on the “**History**” tab located in mid-section of the summary page
  - Review the changes and comments from the PI

After reviewing the response to comments, you will have 3 options: Request changes, Approve, or Terminate the project.

- Under **My Activities** section of a study’s workspace
  - Click on **Changes Requested**
    - OSIRIS sends an email notification to the PI and Study Coordinator
    - The process of requesting changes unlocks the project and allows the PI to make the requested changes
  - Click on **Approve**
    - A text box is available to make comments if needed
  - Click on **Terminate** study
    - The project is disapproved and no further review will occur

- Remember to click **OK** to save your work before closing the window
- The ancillary reviewer will continue to have access to the project if needed

**You have now reviewed the project, made a determination, and completed your role as an ancillary reviewer.**

### General Comments

- “**Send Comments to Study Team**”
  - Be careful when using this link as this is just an FYI comment which does not require any action

- If you are requesting changes to the application
  - Go to **“My Activities”** and click on **“Changes Requested by Ancillary Reviewer”**

- Please note: The system is locked down once the PI clicks on the submit button and the research team is not able to make any changes unless a reviewer requests one

- Be careful not to approve a project until all the **requested changes have been verified**